

REMARKS

Claims 1-10 are all the claims pending in the application; claims 1, 2 and 10 have been rejected; claims 3-9 have been withdrawn from consideration.

Upon entry of this Amendment, claims 3-9 will be canceled, claim 11 will be added, and claims 1-2 and 10-11 will be pending.

Support for the amendment of claim 1 to recite homologues having 95% identity to a polypeptide comprising SEQ ID NO:3 may be found at page 6, second paragraph, of the specification.

Support for the amendment of claim 1 to recite the activity of the homologues (i.e., regulation of neural dendrite spread) finds support at page 22, first paragraph, of the specification.

No new matter has been added. Entry of the Amendment is respectfully requested.

I. Restriction/Election of Species Requirement

At paragraph 3 of the Office Action, the Examiner acknowledges Applicants' provisional election without traverse of Group I (claims 1, 2, and 10) drawn to an isolated polypeptide, and Group A (SEQ ID NOs: 3 and 4) drawn to the polypeptide sequences of clone OC001.

As the Examiner requests affirmation of the election, Applicants hereby confirm the election.

II. Objections to the Specification

A. At paragraph 5 of the Office Action, the Abstract is objected to because it is not limited to a single paragraph.

Included herewith is an amendment to the Abstract. In view of the amendment to the Abstract, Applicants respectfully request reconsideration and withdrawal of this objection.

B. At paragraph 6a of the Office Action, the Examiner states that the specification should be updated to reflect the issued status of the parent application.

Included herewith is an amendment to the specification, updating the priority information. In view of the amendment to the specification, Applicants respectfully request reconsideration and withdrawal of this objection.

C. At paragraph 6b of the Office Action, the Examiner objects to the title of the invention as not being descriptive. The Examiner suggests replacement of the current title with “An Isolated OC001 Polypeptide.”

Included herewith is an amendment to the title in the manner proposed by the Examiner. In view of the amendment to the title, Applicants respectfully request reconsideration and withdrawal of this objection.

III. Objections to the Claims

At paragraph 7 of the Office Action, claims 1, 2 and 10 are objected to for the following reasons.

a. In claims 1 and 2, the phrase “SEQ ID NOS.” should be amended to recite “SEQ ID NOs:”.

b. Claim 10 recites a non-elected invention and should be amended to cancel the dependency to claim 9.

c. In line 2 of claim 10, the word “a” should follow “with.”

Included herewith are amendments to the claims in the manner proposed by the Examiner. In view of the amendments to the claims, Applicants respectfully request reconsideration and withdrawal of these objections.

IV. Claim Rejections Under 35 U.S.C. § 101

At paragraph 8 of the Office Action, claims 1, 2, and 10 are rejected under 35 U.S.C. § 101 as not supported by either a credible, specific and substantial asserted utility, or a well established utility.

The Examiner states that the specification does not teach any significant or functional characteristics of the claimed isolated forms of the OC001 polypeptide, comprising the amino acid sequences shown in SEQ ID NOs: 3 and 4.

Applicants respectfully traverse the Examiner's position and assert that the OC001 polypeptide has a specific, substantial and credible utility that is based on the spread activity the polypeptide has on neural dendrites, as well as the neurite outgrowth activity of the polypeptide, as supported by the description in the instant specification and the two publications discussed below.

As disclosed in the first full paragraph at page 28 of the specification, the OC001 polypeptide of the present application is structurally similar to rat neurotrimin and human opioid-binding cell adhesion molecule (OBCAM) (see enclosed documents D1 and D2). Indeed, the OC001 polypeptide has now been confirmed to be human neurotrimin. Neurotrimins comprise the IgLON family of neural cell adhesion molecules and share similar activities.

Gil et al. (J. Neuroscience, 1998, 18(22):9312-9325, enclosed herewith) discloses that members of the neurotrimin family have activity in the promotion of outgrowths of certain neurons, inhibition of outgrowths by other types of neurons, and regulation of the development of neuronal projections. Further, Wilson et al. (J. Cell Science, 1996, 109:3129-3138, enclosed herewith) described prior to the filing of the instant application that GP55-A, which is 73% similar to neurotrimin (see Table 1 of Wilson et al.), inhibits neurite outgrowth.

In light of these points, it is clear that the skilled artisan would understand that the OC001 polypeptide of the present application is a member of the IgLON family, and that the OC001 polypeptide would be expected to have activity in the regulation of neuron outgrowth. The outgrowth of neurons is synonymous with "spread of neural dendrites" that is disclosed at page 22, first paragraph, of the specification.

Accordingly, Applicants respectfully assert that the OC001 polypeptide is supported by a specific, substantial and credible utility under 35 U.S.C. §101, and respectfully request reconsideration and withdrawal of this rejection.

V. Claim Rejections Under 35 U.S.C. §112

A. At paragraphs 9 and 9a of the Office Action, claims 1, 2, and 10 are rejected under 35 U.S.C. § 112, first paragraph as lacking adequate written description support in the specification as filed.

(1) The Examiner states that because the claims are not supported by either a specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the invention.

(2) The Examiner further states that even if the claims were supported by a credible, specific and substantial asserted utility or a well established utility, they would remain rejected as lacking written description support because the Examiner has interpreted the phrases “an isolated form,” “the amino acid sequence shown in SEQ ID NOs: 3 and 4,” and “homologue thereof, fragment thereof or homologue of the fragment” as reading upon amino acid fragments of SEQ ID NOs: 3 and 4 and amino acid variants with any number of deletions, substitutions, or additions. The Examiner reasons that because the specification does not support any such variant, fragment, derivative, or homolog of the OC001 polypeptide other than the full-length amino acid sequences of SEQ ID NOs: 3 and 4, the claims are not adequately supported.

As to the first portion of the rejection, Applicants refer to the comments above, establishing a specific, substantial and credible utility under 35 U.S.C. §101.

As to the second portion of the rejection, included herewith is an amendment to the claims such that recitation of fragments and homologues of the fragments have been canceled from the claims. The claims now recite a small, well-defined genus of polypeptides based on both structural and functional characteristics. As such, the skilled artisan could readily envision the members of the claimed genus, and the claims have adequate written description support in the specification as filed.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

B. At paragraph 9b of the Office Action, claim 10 is rejected under 35 U.S.C. §112, first paragraph, as lacking adequate written description support.

The Examiner states that the specification does not teach how to use a pharmaceutical composition comprising the OC001 polypeptide for the treatment of a disease or disorder in an

animal without undue experimentation. The Examiner notes that this rejection could be overcome by canceling the term “pharmaceutical” from claim 10.

Included herewith is an amendment to claim 10 in the manner suggested by the Examiner. In view of the amendment, claim 10 has adequate written description support in the specification as filed and Applicants respectfully request reconsideration and withdrawal of this rejection.

C. At paragraph 10 of the Office Action, claims 1, 2, and 10 are rejected under 35 U.S.C. §112, first paragraph, lacking adequate written description support in the specification as filed.

The Examiner explains that because the claims do not require the OC001 polypeptide to possess any particular biological activity, nor any conserved structure, or other disclosed distinguishing feature, the claims are drawn to a broad genus of polypeptides, of which only one member (OC001) is disclosed. As such, the Examiner is of the position that Applicants were not in possession of the genus as broadly claimed at the time the application was filed.

As discussed above, the claims have been amended to recite a small genus of well-defined polypeptides. Accordingly, the claims have adequate written description support in the specification as filed and Applicants respectfully request reconsideration and withdrawal of this rejection.

D. At paragraph 12 of the Office Action, claims 1, 2, and 10 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

(1) The Examiner states that the term “form” in claims 1, 2, and 10 is a relative term and because the term is not defined by the claims or in the specification, nor is reasonably appraisable by a skilled artisan, the claims are rendered indefinite.

(2) The Examiner also states that claim 10 is indefinite because the elements recited in the claim do not constitute proper Markush groups.

Included herewith is an amendment to claims, whereby each of the issues raised by the Examiner has been addressed, thus making the claims definite as written. In view of the amendments, Applicants respectfully request reconsideration and withdrawal of this rejection.

VI. Claim Rejections Under 35 U.S.C. §102

At paragraph 14 of the Office Action, claims 1, 2, and 10 are rejected under 35 U.S.C. §102(b) as being anticipated by Struyk et al. (*J. Neurosci.* 15(3):2141-2156 (1995)).

Initially, the Examiner notes that she has broadly interpreted the phrases “an isolated form,” “the amino acid sequence shown in SEQ ID NOs: 3 and 4,” and “homologue thereof, fragment thereof or homologue of the fragment” as reading upon amino acid fragments of SEQ ID NOs: 3 and 4 and amino acid variants with any number of deletions, substitutions, or additions.

The Examiner contends that Struyk teaches an isolated polypeptide termed “neurotrimin” that is 90.8% identical to the claimed polypeptide of SEQ ID NO: 3, and 98.4% identical to the claimed polypeptide of SEQ ID NO: 4.

Homologues of SEQ ID NO:4, fragments, and homologues of fragments are no longer recited in the claims, thus making the rejection moot as to these claim elements.

Included herewith is an amendment to the claims such that the claims recite homologues having at least 95% identity with the polypeptide of SEQ ID NO:3. As the polypeptide of Struyk has only 90.8% identity, Struyk does not teach each and every element of the claims and thus does not anticipate the claims.

In view of the amendments and these comments, Struyk does not teach each and every limitation of the claims and Applicants respectfully request reconsideration and withdrawal of this rejection.

VII. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. §1.111
U.S. Appln. No. 10/657,103

Q77131

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: November 7, 2006

DOCUMENT D1

ClustalW Result

Tue Nov 7 11:04:23 JST 2006

CLUSTAL W (1.83) Multiple Sequence Alignments

Sequence format is Pearson
 Sequence 1: OC001 344 aa
 Sequence 2: rat_neurotrimin_U16845_ 345 aa
 Start of Pairwise alignments
 Aligning...
 Sequences (1:2) Aligned. Score: 68
 Guide tree file created: [/tmp/1581.dnd]
 Start of Multiple Alignment
 There are 1 groups
 Aligning...
 Group 1: Sequences: 2 Score: 6331
 Alignment Score 1480
 CLUSTAL-Alignment file created [/tmp/1581.aln]

CLUSTAL W (1.83) multiple sequence alignment

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OC001          MKTIQPKMHNSISWAIFTGLAALCLF-QGVPVRSGLATFPKAMDNVTVRQ
rat_neurotrimin_U16845_ -MGVCGYLFLPWKCLVVVSLRLLFLVPTGVPVRSGLATFPKAMDNVTVRQ
                        :  . . . :...* * .  *****
OC001          GESATLRCTIDNRVTRVAWLNRSTILYAGNDKWCLDPRVLLSNTQTQYS
rat_neurotrimin_U16845_ GESATLRCTIDNRVTRVAWLNRSTILYAGNDKWSIDPRVIILVNTPTQYS
                        *****:*****.:****:* ** ****
OC001          IEIQNVVDVYDEGPYTCVQTDNHPKTSRVHLIVQVSPKIVEISSDISINE
rat_neurotrimin_U16845_ IMIQNVVDVYDEGPYTCVQTDNHPKTSRVHLIVQVPPQIMNISSDITVNE
                        * *****.:*:*:*****:***
OC001          GNNISLTCIATGRPEPTVTWRHISPK-AVG FVSEDEYLEIQGITREQSGD
rat_neurotrimin_U16845_ GSSVTLLCLAIGRPEPTVTWRHLSVKEGQGFVSEDEYLEISDIKRDQSGE
                        *...:* *:* *****:* * . *****.:*:*:***
OC001          YECSASNDVAAPVRRVKVTVNYPPIYISEAKGTGVPVGQKGTQCEASAV
rat_neurotrimin_U16845_ YECSALNDVAAPDVRKVKITVNYPPIYISKAKNTGVS VGQKGILSCEASAV
                        ***** ***** *:***:*****:***.***.***** *.*****
OC001          PSAEFQWYKDDKRLIEGKKGVKVENRPFLSKLIFFNVSEHDYGN YTCVAS
rat_neurotrimin_U16845_ PMAEFQWFKEETRLATGLDGMRIENKGRMSTLTFFNVSEKDYGN YTCVAT
                        * *****:*.:.** * .:***: :*. * *****:*****:
OC001          NKLGHNTNASIMLFGPGAVSEVSNGTSRRAGCVWLLPLLVLHLLKLF
rat_neurotrimin_U16845_ NKLGHNTNASITLYGPGAVIDGVNSASRALACLWLSGTLLAHFFIKF
                        ****:***** *:***** : *.*** .:*** *:***:***

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>OC001
MKTIQPKMHNSISWAIFTGLAALCLFQGVPVRSGLATFPKAMDNVTVRQGESATLRCTID
NRVTRVAWLNRSTILYAGNDKWCLDPRVLLSNTQTQYSIEIQNVVDVYDEGPYTCVQTD
NHPKTSRVHLIVQVSPKIVEISSDISINEGNNISLTCIATGRPEPTVTWRHISPKAVGFV
SEDEYLEIQGITREQSGDYECASNDVAAPVRRVKVTVNYPPIYISEAKGTGVPVGQKGT

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LQCEASAVPSAEFQWKDDKRLIEGKKGVKVENRPFLSKLIFFNVSEHDYGNITCVASNK
LGHTNASIMLFGPGAVSEVSNGTSSRRAGCVWLLPLLVLHLLLK
>rat_neurotrimin(U16845)
MGVCGYLFLPWKCLVVVSLRLLFLVPTGVPVRSGBATFPKAMDN
VTVRQGESATLRCTIDDRVTRVAWLNRSITLYAGNDKWSIDPRVIILVNTPTQYSIMI
QNVDVYDEGPYTCVQTDNHPKTSRVHLIVQVPPQIMNISSDITVNEGSSVTLLCLAI
GRPEPTVTWRHLSVKEGQGFVSEDEYLEISDIKRDQSGEYECALNDVAAPDVRKVKI
TVNYPPYISKAKNTGVSQGKILSCEASAVPMAEFQWFKEETRLATGLDGMRIENKG
RMSTLTFFNVSEKDYGNITCVATNKLGNSTNASTLYGPGAVIDGVNSASRALACLWLS
GTLLAHFFIKF

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DOCUMENT 02

ClustalW Result

Tue Nov 7 11:05:49 JST 2006

CLUSTAL W (1.83) Multiple Sequence Alignments

Sequence format is Pearson
 Sequence 1: OC001 344 aa
 Sequence 2: human_OBCAM_L34774_ 344 aa
 Start of Pairwise alignments
 Aligning...
 Sequences (1:2) Aligned. Score: 89
 Guide tree file created: [/tmp/1584.dnd]
 Start of Multiple Alignment
 There are 1 groups
 Aligning...
 Group 1: Sequences: 2 Score: 7089
 Alignment Score 1911
 CLUSTAL-Alignment file created [/tmp/1584.aln]

CLUSTAL W (1.83) multiple sequence alignment

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OC001          MKTIQPKMHNSISWAIIFTGLAALCLF-QGVPVRSGDATFPKAMDNVTVRQGESATLRCTI
human_OBCAM_L34774_ -MGVCGYLFLPWKCLVVVSLRLLFLVPTGVPVRSGDATFPKAMDNVTVRQGESATLRCTI
                  :  . . . :...* * .  *****

OC001          DNRVTRVAWLNRSTILYAGNDKWCLDPRVLLSNTQTQYSIEIQNVVDVYDEGPYTCVQQT
human_OBCAM_L34774_ DNRVTRVAWLNRSTILYAGNDKWCLDPRVLLSNTQTQYSIEIQNVVDVYDEGPYTCVQQT
                  *****

OC001          DNHPKTSRVHLIVQVSPKIVEISSDISINEGNNISLTTCIATGRPEPTVTWRHISPKAVGF
human_OBCAM_L34774_ DNHPKTSRVHLIVQVSPKIVEISSDISINEGNNISLTTCIATGRPEPTVTWRHISPKAVGF
                  *****

OC001          VSEDEYLEIQGITREQSGDYECASNDVAAPVVRVKVTVNYPPIYISEAKGTGVPVGQKG
human_OBCAM_L34774_ VSEDEYLEIQGITREQSGEYECASNDVAAPVVRVNVTVNYPPIYISEAKGTGVPVGQKG
                  *****:*****:*****

OC001          TLQCEASAVPSAEFQWKDDKRLIEGKKGVKVENRPFLSKLIFFNVSEHDYGNITCVASN
human_OBCAM_L34774_ TLQCEASAVPSAEFQWKDDKRLVEGKKGVKVENRPFLSRLTFFNVSEHDYGNITCVASN
                  *****:*****:*****:* *****

OC001          KLGHNASIMLFGPGAVSEVSNGTSSRRAGCVWLLPLLVLHLLLK
human_OBCAM_L34774_ KLGHNASIMLFGPGAVSEVNNGTSSRRAGCIWLLPLLVLHLLLK
                  *****:*****:*****

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>OC001
MKTIQPKMHNSISWAIIFTGLAALCLFQGVPVRSGDATFPKAMDNVTVRQGESATLRCTID
NRVTRVAWLNRSTILYAGNDKWCLDPRVLLSNTQTQYSIEIQNVVDVYDEGPYTCVQTD
NHPKTSRVHLIVQVSPKIVEISSDISINEGNNISLTTCIATGRPEPTVTWRHISPKAVGFV
SEDEYLEIQGITREQSGDYECASNDVAAPVVRVKVTVNYPPIYISEAKGTGVPVGQKGT
LQCEASAVPSAEFQWKDDKRLIEGKKGVKVENRPFLSKLIFFNVSEHDYGNITCVASNK
LGHTNASIMLFGPGAVSEVSNGTSSRRAGCVWLLPLLVLHLLLK
>human_OBCAM(L34774)
MGVCGYLFLPWKCLVVVSLRLLFLVPTGVPVRSGDATFPKAMDN

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VTVRQGESATLRCTIDNRVTRVAWLNRSTILYAGNDKWCLDPRVVLLSNTQTQYSIEI
QNVDVYDEGPYTCSVQTDNHPKTSRVHLIVQVSPKIVEISSDISINEGNNISLTCIAT
GRPEPTVTWRHISPKAVGFVSEDEYLEIQGITREQSGEYECSASNDVAAPVVRVNVVT
VNYPPISEAKGTGVPVGQKGTQCEASAVPSAEFQWFKDDKRLVEGKKGVKVENRPF
LSRLTFFNVSEHDYGNYTCVASNKLGHTNASIMLFGPGAVSEVNNGTSRRAGCIWLLP
LLVLHLLKLF